DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 3, 2015

U & I Corporation
Mr. Young-Geun Kim
Regulatory Affairs Specialist
20, Sandan-ro 76 beon-gil (Road)
Uijeongbu-si, Gyeonggi-do
Republic of Korea 480-859

Re: K143631
Trade/Device Name: Benefix™ Interspinous Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: August 17, 2015
Received: August 19, 2015

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143631

Device Name
Benefix™ Interspinous Fixation System

Indications for Use *(Describe)*
Benefix™ Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for single level use in the non-cervical spine (T1-S1). It is intended for single level plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. Benefix™ Interspinous Fixation System is intended for use with bone graft material and is not intended for stand-alone use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Manufacturer:	U & I Corporation 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859
Sponsor:	U & I Corporation 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859
Sponsor Contact:	Young-Geun Kim, Regulatory Affairs Specialist +82 31 860 6836 ygkim@youic.com
Date Prepared:	Aug 17, 2015
Trade Name:	**Benefix™ Interspinous Fixation System**
Device Classification:	Class II
Classification Name:	Spinal interlaminal fixation orthosis, per 21 CFR 888.3050
Common Name:	Spinous Process Plate
Product Code:	PEK
Primary Predicate:	X-Spine Systems AXLE™ Interspinous Fusion System (K130438)
Additional Predicates:	Medtronic CD Horizon SPIRE™ Stabilization System (K043053) Lanx Aspen™ Spinous Process System (K090252)

Description of Device:

Benefix™ Interspinous Fixation System is manufactured by U&I Corporation. The System consists of various barrels, plates, and set screws. All implant components are made of titanium alloy in accordance with ASTM F136. **Benefix™ Interspinous Fixation System** is intended to provide immobilization and stabilization of the spinous processes to support fusion. The components can be assembled in a various configurations so that adaptations can be made to take into pathology and

individual patient anatomy. All implants are intended for single use only and should not be reused under any circumstances.

Indications for Use:

Benefix™ Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for single level use in the non-cervical spine (T1-S1). It is intended for single level plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. **Benefix™ Interspinous Fixation System** is intended for use with bone graft material and is not intended for stand-alone use.

Substantial Equivalence:

Benefix™ Interspinous Fixation System is substantially equivalent to AXLE™ Interspinous Fusion System, CD Horizon SPIRE™ Stabilization System, Aspen™ Spinous Process System in design, material, mechanical performance, function and intended use.

Benefix™ Interspinous Fixation System has an extension design that is similar to AXLE™ Interspinous Fusion System. **Benefix™ Interspinous Fixation System** is relying on AXLE™ Interspinous Fusion, which has the same intended use as the **Benefix™ Interspinous Fixation System**, to support substantial equivalence with respect to technological characteristics.

1. Comparison of Technological Characteristics

The predicates and proposed device have the similar intended use and basic fundamental scientific technology and share the following similarities;

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials
- The equivalent mechanical performance

2. Performance Testing

Benefix™ Interspinous Fixation System was tested in a non-clinical setting (bench testing), and the test results demonstrated that the **Benefix™ Interspinous Fixation System** is substantially equivalent to the predicate devices.

The following tests were performed:

(1) Static compression bending test using a modified version of ASTM F1717
(2) Static torsion test using a modified version of ASTM F1717.
(3) Compression bending fatigue test using a modified version of ASTM F1717
(4) Spike pull-off test
(5) Locking mechanism strength test

3. Conclusion

The data and information provided in this submission support the conclusion that the **Benefix™ Interspinous Fixation System** is substantially equivalent to the predicate devices.